SECTION 5: 510(k) Summary

K072754

Submitter: Axenic Dental, Inc.
259 East Michigan
Suite 409, 4th Floor
Kalamazoo, MI 49007

Contact: Joseph T. Sobota, M.D.
269-349-8870

JAN 25 2008

Name of Device: Axenic Dental DHP™, Disposable High-Performance Handpiece

Predicate Device: OralSafe™ Disposable Handpieces, K923469

Description of the New Device: The Axenic Dental, Inc. DHP™ "Disposable High-Performance Handpiece" is a sterile, single patient use, disposable instrument that is substantially equivalent to standard, re-usable, metal or plastic handpieces. All Axenic DHP™, high-speed, dental hand pieces are designed to operate at maximum specification outputs for 12 to 14 minutes of use. The single patient use nature of the instrument precludes any necessity for maintenance, cleaning, or sterilization.

INTENDED USE OF THE NEW DEVICE: The Axenic Dental, Inc. DHP™ "Disposable High-Performance" handpiece, with appropriate burs, is indicated for all dental practice procedures for which metal handpieces are used, including cutting, shaping and preparing teeth for cavity repair, crowns and bridges. The device is suitable for use in circumstances where infectious inter-patient contamination is a concern. The device can be used for duration of 12 to 14 minutes cutting time during single patient use.

Comparison of the Technological Features of the New [Modified] Device and Predicate Devices: The modified device and the lawfully marketed predicate device contain similar materials of construction. Features of the modified device are comparable to those of the predicate device with the exception that the modified device includes sterility and pyrogen free indications and is maintenance free. These enhancements will not negatively affect the safety or effectiveness of the device.

Signed,

Joseph T. Sobota, M.D.
Chief Regulatory Executive
Axenic Dental, Inc.

DHP™ is a Registered Trademark of Axenic Dental, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Mr. Joseph Sobota
Chief Regulatory Executive
Axenic Dental, Incorporated
295 East Michigan
Suite 409, 4th Floor
Kalamazoo, Michigan 49007

Re: K072754
Trade/Device Name: Axenic DHP™ "Disposable High-Performance" Handpiece, Model DHP™
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: January 18, 2008
Received: January 22, 2008

Dear Mr. Sobota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

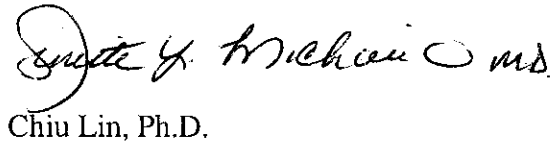
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INSTRUCTIONS FOR USE

510(k) Number: K072754

Device Name: Axenic DHP™ "Disposable High-Performance" Handpiece, Model DHP™

The Axenic Dental, Inc. DHP™ "Disposable High-Performance" sterile, pyrogen free, maintenance free handpiece, with appropriate burs, is indicated for all dental practice procedures for which metal handpieces are used, including cutting, shaping and preparing teeth for cavity repair, crowns and bridges. The device is suitable for use in circumstances where infectious, inter-patient contamination is a concern. The device can be used for duration of 12 to 14 minutes cutting time during single patient use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **or Over-the-Counter Use** _____ **(Per 21 CFR 801.109)**

For Professional Use Only (Dental Health Provider) X

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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